

General

Guideline Title

Clinical practice guideline: tympanostomy tubes in children.

Bibliographic Source(s)

Rosenfeld RM, Schwartz SR, Pynnonen MA, Tunkel DE, Hussey HM, Fichera JS, Grimes AM, Hackell JM, Harrison MF, Haskell H, Haynes DS, Kim TW, Lafreniere DC, LeBlanc K, Mackey WL, Nettekville JL, Pipan ME, Raol NP, Schellhase KG. Clinical practice guideline: tympanostomy tubes in children. *Otolaryngol Head Neck Surg*. 2013 Jul;149(1 Suppl):S1-35. [138 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The evidence grades (A-D, X) and evidence-based statements (Strong Recommendation, Recommendation, Option, and No Recommendation) are defined at the end of the "Major Recommendations" field.

Statement 1. Otitis Media with Effusion (OME) of Short Duration

Clinicians should *not* perform tympanostomy tube insertion in children with a single episode of OME of less than 3 months' duration, from the date of onset (if known) or from the date of diagnosis (if onset is unknown).

Recommendation against based on systematic review of observational studies of natural history and an absence of any randomized controlled trials on efficacy of tubes for children with OME less than 2 to 3 months' duration and a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on a systematic review of observational studies and control groups in randomized controlled trials (RCTs) on the natural history of OME and an absence of any RCTs on efficacy of tympanostomy tubes for children with OME less than 2 months' duration
- Level of confidence in evidence: High
- Benefits: Avoidance of unnecessary surgery and its risks, avoidance of surgery in children for whom the benefits of tympanostomy tubes have not been studied and are uncertain, avoidance of surgery in children with a condition that has reasonable likelihood of spontaneous resolution, cost savings
- Risks, harms, costs: Delayed intervention in children who do not recover spontaneously and/or in children who develop recurrent episodes

of middle ear effusion (MEE)

- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Exclusion of children with OME of less than 2 months' duration from all published RCTs of tube efficacy was considered compelling evidence to question the value of surgery in this population, especially considering the known risks of tympanostomy tube surgery
- Intentional vagueness: None
- Role of patient (caregiver) preferences: Limited, because of good evidence that otherwise healthy children with OME of short duration do not benefit from tympanostomy tube insertion
- Exceptions: At-risk children (see Table 2 in the original guideline document); see Statements 6 and 7 for explicit information on at-risk children
- Policy level: Recommendation
- Differences of opinion: None

Statement 2. Hearing Testing

Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion.

Recommendation based on observational and cross-sectional studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational and cross-sectional studies assessing the prevalence of conductive hearing loss with OME
- Level of confidence in evidence: High
- Benefits: Documentation of hearing status, improved decision making regarding the need for surgery in chronic OME, establishment of baseline hearing prior to surgery, detection of coexisting sensorineural hearing loss
- Risks, harms, costs: Cost of the audiologic assessment
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: The words *age-appropriate audiologic testing* are used to recognize that the specific methods will vary with the age of the child, but a full discussion of the specifics of testing is beyond the scope of this guideline
- Role of patient (caregiver) preferences: Some, caregivers may decline testing
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 3. Chronic Bilateral OME with Hearing Difficulty

Clinicians should offer tympanostomy bilateral tube insertion to children with bilateral OME for 3 months or longer AND documented hearing difficulties.

Recommendation based on randomized controlled trials and observational studies, with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, based on well-designed RCTs showing reduced MEE prevalence and improved hearing after tympanostomy tube insertion; observational studies documenting improved quality of life (QOL); and extrapolation of research and basic science principles for optimizing auditory access
- Level of confidence in the evidence: High
- Benefits: Reduced prevalence of MEE, improved hearing, improved child and caregiver QOL, optimization of auditory access for speech and language acquisition, elimination of a potential barrier to focusing and attention in a learning environment
- Risks, harms, costs: Risk of anesthesia, sequelae of the indwelling tympanostomy tubes (e.g., otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), failure of or premature tympanostomy tube extrusion, tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Assumption that optimizing auditory access would improve speech and language outcomes, despite inconclusive evidence regarding the impact of MEE on speech and language development
- Intentional vagueness: The term *hearing difficulty* is used instead of *hearing loss* to emphasize that a functional assessment of how a child

uses hearing and engages in their environment is important, regardless of what specific threshold is used to define hearing loss based on audiologic criteria

- Role of patient (caregiver) preferences: Substantial role for shared decision making regarding the decision to proceed with, or to decline, tympanostomy tube insertion
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: Minor differences regarding the role of caregiver report as a surrogate for audiologic assessment and whether the action taken by the clinician should be to "recommend" tubes (minority opinion) versus to "offer" tubes (majority opinion)

Statement 4. Chronic OME with Symptoms

Clinicians may perform tympanostomy tube insertion in children with unilateral or bilateral OME for 3 months or longer (chronic OME) AND symptoms that are likely attributable to OME that include, but are not limited to, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life.

Option based on randomized controlled trials and before-and-after studies with a balance between benefit and harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on before-and-after studies on vestibular function and QOL, RCTs on reduced MEE after tubes for chronic OME, and observational studies regarding the impact of MEE on children as related, but not limited to, school performance, behavioral issues, and speech delay
- Level of confidence in evidence: High for vestibular problems and QOL; medium for poor school performance, behavioral problems, and ear discomfort, because of study limitations and the multifactorial nature of these issues
- Benefits: Reduced prevalence of MEE, possible relief of symptoms attributed to chronic OME, elimination of MEE as a confounding factor from efforts to understand the reason or cause of a vestibular problem, poor school performance, behavioral problem, or ear discomfort
- Risks, harms, costs: None related to offering surgery, but if performed, tympanostomy tube insertion includes risks from anesthesia, sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), premature tympanostomy tube extrusion, retained tympanostomy tube, tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs
- Benefit-harm assessment: Equilibrium
- Value judgments: Chronic MEE has been associated with problems other than hearing loss; intervening when MEE is identified can reduce symptoms. The group's confidence in the evidence of a child benefitting from intervention was insufficient to conclude a preponderance of benefit over harm and instead found at equilibrium
- Intentional vagueness: The words *likely attributable* are used to reflect the understanding that the symptoms listed may have multifactorial causes, of which OME may be only one factor, and resolution of OME may not necessarily resolve the problem
- Role of patient (caregiver) preferences: Substantial role for shared decision making regarding the decision to proceed with, or to decline, tympanostomy tube insertion
- Exceptions: None
- Policy level: Option
- Differences of opinion: None

Statement 5. Surveillance of Chronic OME

Clinicians should reevaluate, at 3- to 6-month intervals, children with chronic OME who do not receive tympanostomy tubes, until the effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected.

Recommendation based on observational studies, with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High
- Benefits: Detection of structural changes in the tympanic membrane that may require intervention, detection of new hearing difficulties or symptoms that would lead to reassessing the need for tympanostomy tube insertion, discussion of strategies for optimizing the listening-learning environment for children with OME, as well as ongoing counseling and education of parents/caregiver
- Risks, harms, costs: Cost of examination(s)
- Benefit-harm assessment: Preponderance of benefit over harm

- Value judgments: Although it is uncommon, untreated OME can cause progressive changes in the tympanic membrane that require surgical intervention. There was an implicit assumption that surveillance and early detection/intervention could prevent complications and would also provide opportunities for ongoing education and counseling of caregivers
- Intentional vagueness: The surveillance interval is broadly defined at 3 to 6 months to accommodate provider and patient preference; "significant" hearing loss is broadly defined as one that is noticed by the caregiver, reported by the child, or interferes in school performance or QOL
- Role of patient (caregiver) preferences: Opportunity for shared decision making regarding the surveillance interval
- Exceptions: None
- Policy level: Recommendation
- Difference of opinion: None

Statement 6. Recurrent Acute Otitis Media (AOM) without MEE

Clinicians should *not* perform tympanostomy tube insertion in children with recurrent AOM who do not have MEE in either ear at the time of assessment for tube candidacy.

Recommendation against based on systematic reviews and randomized controlled trials with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade A, based on a meta-analysis of RCTs, a systematic review of RCT control groups regarding the natural history of recurrent AOM, and other RCTs
- Level of confidence in evidence: High
- Benefits: Avoid unnecessary surgery and its risks, avoid surgery in children for whom RCTs have not demonstrated any benefit for reducing AOM incidence or in children with a condition that has reasonable likelihood of spontaneous resolution, cost savings
- Risks, harms, costs: Delay in intervention for children who eventually require tympanostomy tubes, need for systemic antibiotics among children who continue to have episodes of recurrent AOM
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Implicit in this recommendation is the ability to reassess children who continue to have AOM despite observation and to perform tympanostomy tube insertion if MEE is present (Statement 7); risk of complications or poor outcomes from delayed tube insertion for children who continue to have recurrent AOM is minimal
- Intentional vagueness: The method of confirming the absence of MEE should be based on clinician experience and may include tympanometry, simple otoscopy, and/or pneumatic otoscopy
- Role of patient (caregiver) preferences: Limited, because of favorable natural history and good evidence that otherwise healthy children with recurrent AOM without MEE do not have a reduced incidence of AOM after tympanostomy tube insertion
- Exceptions: At-risk children (see Table 2 in the original guideline document), children with histories of severe or persistent AOM, immunosuppression; prior complication of otitis media (mastoiditis, meningitis, facial nerve paralysis); multiple antibiotic allergy or intolerance
- Policy level: Recommendation
- Differences of opinion: None

Statement 7. Recurrent AOM with MEE

Clinicians should offer bilateral tympanostomy tube insertion in children with recurrent AOM who have unilateral or bilateral MEE at the time of assessment for tube candidacy.

Recommendation based on randomized controlled trials with minimal limitations and a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, based on RCTs with minor limitations
- Level of confidence in evidence: Medium; some uncertainty regarding the magnitude of clinical benefit and importance, because of heterogeneity in the design and outcomes of clinical trials
- Benefits: Mean decrease of approximately 3 episodes of AOM per year, ability to treat future episodes of AOM with topical antibiotics instead of systemic antibiotics, reduced pain with future AOM episodes, improved hearing during AOM episodes
- Risks, harms, costs: Risks from anesthesia, sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), premature tympanostomy tube extrusion, retained tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs
- Benefit-harm assessment: Preponderance of benefit over harm

- Value judgments: In addition to the benefits seen in RCTs, the presence of effusion at the time of assessment served as a marker of diagnostic accuracy for AOM
- Intentional vagueness: The method of confirming the presence of middle ear effusion should be based on clinician experience and may include tympanometry, simple otoscopy, and/or pneumatic otoscopy
- Role of patient (caregiver) preferences: Substantial role for shared decision making regarding the decision to proceed with, or to decline, tympanostomy tube insertion
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 8. At Risk Children

Clinicians should determine if a child with recurrent AOM or with OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors (see Table 2 in the original guideline document).

Recommendation based on observational studies with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational studies
- Level of confidence in evidence: High for Down syndrome, cleft palate, and permanent hearing loss; medium for other risk factors
- Benefits: Facilitation of future decisions about tube candidacy, identification of children who might benefit from early intervention (including tympanostomy tubes), identification of children who might benefit from more active and accurate surveillance of middle ear status as well as those who require more prompt evaluation of hearing, speech, and language
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Despite the limited high-quality evidence about the impact of tubes on this population (nearly all RCTs exclude children who are at risk), the panel considered it important to use at-risk status as a factor in decision making about tube candidacy, building on recommendations made in the OME guideline. The panel assumed that at-risk children would be less likely to tolerate OME or recurrent AOM than would the otherwise healthy child
- Intentional vagueness: None
- Role of patient (caregiver) preferences: None, since this recommendation deals only with acquiring information to assist in decision making
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 9. Tympanostomy Tubes and At-Risk Children

Clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is unlikely to resolve quickly as reflected by a type B (flat) tympanogram or persistence of effusion for 3 months or longer.

Option based on a systematic review and observational studies with a balance between benefit and harm.

Action Statement Profile

- Aggregate evidence quality: Grade C based on a systematic review of cohort studies regarding natural history of type B tympanograms and observational studies examining the impact of MEE on at-risk children
- Level of confidence in evidence: Moderate to low, because of methodological concerns with the conduct, outcome reporting, and follow-up of available observational studies.
- Benefits: Improved hearing, resolution of MEE in at risk children who would otherwise have a low probability of spontaneous resolution, mitigates a potential obstacle to child development
- Risks, harms, costs: Risk of anesthesia, sequelae of the indwelling tympanostomy tubes (otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), failure of or premature tympanostomy tube extrusion, tympanostomy tube medialization, procedural anxiety and discomfort, and direct procedural costs
- Benefit-harm assessment: Equilibrium
- Value judgments: Despite the absence of controlled trials identifying benefits of tympanostomy tube placement in at-risk children (such children were excluded from the reviews cited), the panel agreed that tympanostomy tubes were a reasonable intervention for reducing the prevalence of MEE that would otherwise have a low likelihood of prompt spontaneous resolution. Untreated persistent MEE would place

the child at high risk for hearing loss from suboptimal conduction of sound through the middle ear, which could interfere with subsequent speech and language progress

- Intentional vagueness: None
- Role of patient (caregiver) preferences: Substantial role for shared decision making with caregivers regarding whether or not to proceed with tympanostomy tube insertion
- Exclusions: None
- Policy level: Option
- Differences of opinion: None regarding the action statement; a minor difference of opinion about whether children with Down syndrome or cleft palate should be considered independently of children with speech and language delays/disorders

Statement 10. Perioperative Education

In the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications.

Recommendation based on observational studies, with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade C, based on observational studies with limitations
- Level of confidence in evidence: Medium; there is good evidence and strong consensus on the value of patient education and counseling, in general, but evidence on how this education and counseling affect outcomes of children with tympanostomy tubes is limited
- Benefits: Define appropriate caregiver expectations after surgery, enable caregivers to recognize complications early, and improve caregiver understanding of the importance of follow-up
- Risks, harms, costs: None
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of patient education in promoting optimal outcomes
- Intentional vagueness: None
- Role of patient (caregiver) preferences: None, since this recommendation deals only with providing information for proper management
- Exceptions: None
- Policy level: Recommendation
- Differences of opinion: None

Statement 11. Acute Tympanostomy Tube Otorrhea

Clinicians should prescribe topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea.

Strong recommendation based on randomized controlled trials with a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, based on RCTs demonstrating equal efficacy of topical versus oral antibiotic therapy for otorrhea as well as improved outcomes with topical antibiotic therapy when different topical preparations are compared
- Level of confidence in evidence: High
- Benefits: Increased efficacy by providing appropriate coverage of otorrhea pathogens, including *Pseudomonas aeruginosa* and methicillin-resistant *Staphylococcus aureus* (MRSA), avoidance of unnecessary overuse and adverse effects of systemic antibiotics, including bacterial resistance
- Risks, harms, costs: Additional expense of topical otic antibiotics compared with oral antibiotics, potential difficulties in drug delivery to the middle ear if presence of obstructing debris or purulence in the ear canal
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Emphasis on avoiding systemic antibiotics due to known adverse events and potential for induced bacterial resistance
- Intentional vagueness: None
- Role of patient (caregiver) preferences: Limited, because there is good evidence that topical antibiotic eardrops are safer than oral antibiotics and have equal efficacy
- Exceptions: Children with complicated otorrhea, cellulitis of adjacent skin, concurrent bacterial infection requiring antibiotics (e.g., bacterial sinusitis, group A strep throat), or those children who are immunocompromised
- Policy level: Strong recommendation

- Difference of opinion: None

Statement 12. Water Precautions

Clinicians should not encourage routine, prophylactic water precautions (use of earplugs or headbands; avoidance of swimming or water sports) for children with tympanostomy tubes.

Recommendation against based on randomized controlled trials with limitations, observational studies with consistent effects, and a preponderance of benefit over harm.

Action Statement Profile

- Aggregate evidence quality: Grade B, based on 1 randomized controlled trial and multiple observational studies with consistent effects
- Level of confidence in evidence: High
- Benefits: Allows for normal activity and swimming, reduced anxiety, cost savings
- Risk, harm, cost: Potential for slight increase in otorrhea rates in some children
- Benefit-harm assessment: Preponderance of benefit over harm
- Value judgments: Importance of not restricting or limiting children's water activity in the absence of proven, clinically significant benefits of routine water precautions
- Intentional vagueness: The word *routine* is used to soften the recommendation since individual children may benefit from water precautions in specific situations (e.g., lake swimming, deep diving, recurrent otorrhea, head dunking in the bathtub, or otalgia from water entry into the ear canal)
- Role of patient (caregiver) preferences: Significant role in deciding whether or not to use water precautions based on the child's specific needs, comfort level, and tolerance of water exposure.
- Exceptions: Children with tympanostomy tubes and (1) an active episode of otorrhea or (2) recurrent or prolonged otorrhea episodes, as well as those with a history of problems with prior water exposure
- Policy level: Recommendation
- Differences of opinion: None

Definitions:

Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). [*] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). [*] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D) [*] or that well-done studies (grade A, B, or C) [*] show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No	No recommendation means there is both a lack of pertinent evidence (grade D) [*]	Clinicians should feel little

Recommendation Statement	Definition	Implication
	and an unclear balance between benefits and harms.	constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

*See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnostic Tests	Evidence Quality for All Other Studies
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

Clinical Algorithm(s)

The original guideline document includes a clinical algorithm of guideline's key action statements for children with otitis media with effusion.

Scope

Disease/Condition(s)

Diseases and conditions requiring insertion of tympanostomy tubes, such as persistent middle ear fluid, frequent ear infections, or ear infections that persist after antibiotic therapy (e.g., chronic otitis media with effusion, recurrent acute otitis media)

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Treatment

Clinical Specialty

Anesthesiology

Family Practice

Infectious Diseases

Otolaryngology

Pediatrics

Preventive Medicine

Speech-Language Pathology

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

Speech-Language Pathologists

Guideline Objective(s)

To provide clinicians with evidence-based recommendations on patient selection and surgical indications for and management of tympanostomy tubes in children

Target Population

Children, aged 6 months to 12 years (including children considered at risk for developmental delays or disorders), with tympanostomy tubes or being considered for tympanostomy tubes in any care setting, as an intervention for otitis media of any type

Note: This guideline is *not intended* for the following populations:

Children younger than 6 months

Children diagnosed as having retraction-type ear disease (atelectasis or adhesive otitis media), complications of acute otitis media, or barotrauma

Children prescribed medications instilled into the middle ear for conditions such as sudden idiopathic sensorineural hearing loss or Meniere's disease

Children older than 12 years

Interventions and Practices Considered

1. Assessment for tympanostomy tube insertion candidacy based on:
 - Number of episodes of otitis media with effusion (OME)
 - Hearing difficulties
 - Other symptoms attributable to OME
 - Structural abnormalities of the tympanic membrane or middle ear
 - Recurrent episodes of acute otitis media (AOM) with middle ear effusion (MEE)
2. Age-appropriate hearing testing
3. Surveillance of chronic OME before tube insertion

4. Risk assessment for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors
5. Perioperative education of caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications
6. Topical antibiotic eardrops only (without oral antibiotics) for children with uncomplicated acute tympanostomy tube otorrhea
7. Water precautions (e.g., earplugs, headbands, avoidance of swimming or water sports) (recommendation against)

Major Outcomes Considered

- Prevalence and level of hearing loss
- Symptomatology of otitis media with effusion (OME)
- Impact of OME and its sequelae on children (as related, but not limited to school performance, behavioral issues, and speech delay)
- Efficacy of treatment (including, e.g., rate of OME resolution, rate of OME recurrence, need for systemic antibiotics)
- Sequelae and complications tympanostomy
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An information specialist with the Cochrane Ear, Nose, and Throat Disorders Group conducted 2 literature searches using a validated filter strategy. The initial literature search identified clinical practice guidelines, systematic reviews, and meta-analyses related to tympanostomy tubes in children published between 2005 and February 2012. The search was performed in multiple databases including the [National Guideline Clearinghouse](#) , the Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Complementary Medicine Database, Agency for Healthcare Research and Quality, EMBASE, PubMed, Guidelines International Network, Health Services/Technology Assessment Tools, CMA Infobase, National Health Service (NHS) Evidence ENT and Audiology, National Library of Guidelines, National Institute of Clinical Excellence, Scottish Intercollegiate Guidelines Network, New Zealand Guidelines Group, Australian National Health and Medical Research Council, and the TRIP database. The search yielded 10 guidelines and 19 systematic reviews or meta-analyses. After removing duplicates, articles not obviously related to tympanostomy tubes, those not indicating or explicitly stating a systematic review methodology, and non-English language articles, 4 guidelines and 15 systematic reviews or meta-analyses remained.

A second literature search identified randomized controlled trials published between 1980 and March 2012. The following databases were used: MEDLINE, EMBASE, CINAHL, and CENTRAL. The search identified 171 randomized controlled trials. After removing duplicates, non-English language articles, and animal model studies, 113 articles remained.

The following parameters were used to define the search questions:

1. Population: Children
2. Intervention: Tympanostomy tube insertion, including indications for tube placement, preoperative care, and postoperative care
3. Comparison: Any techniques
4. Outcome: Any
5. Setting: Inpatient, outpatient

Final results of both literature searches were distributed to panel members, including electronic full-text versions, if available, of each article. This material was supplemented, as needed, with targeted searches to address specific needs identified in writing the guideline through July 2012.

Number of Source Documents

- 4 guidelines
- 15 systematic reviews or meta-analyses
- 113 randomized controlled trials

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Quality for Grades of Evidence

Grade	Evidence Quality for Diagnostic Tests	Evidence Quality for All Other Studies
A	Systematic review of cross-sectional studies with consistently applied reference standard and blinding	Well-designed randomized controlled trials performed on a population similar to the guideline's target population
B	Individual cross-sectional studies with consistently applied reference standard and blinding	Randomized controlled trials; overwhelmingly consistent evidence from observational studies
C	Nonconsecutive studies, case control studies, or studies with poor, nonindependent, or inconsistently applied reference standards	Observational studies (case control and cohort design)
D	Mechanism-based reasoning or case reports	
X	Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm	

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The evidence-based approach to guideline development requires the evidence supporting a policy be identified, appraised, and summarized and that an explicit link between evidence and statements be defined. Evidence-based statements reflect both the quality of evidence and the balance of benefit and harm that is anticipated when the statement is followed. The definitions for evidence-based statements are listed the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This guideline was developed using an explicit and transparent a priori protocol for creating actionable statements based on supporting evidence and the associated balance of benefit and harm. Members of the panel included a pediatric and adult otolaryngologist, otologist/neurotologist, anesthesiologist, audiologist, family physician, behavioral pediatrician, pediatrician, speech/language pathologist, advanced nurse practitioner, physician assistant, resident physician, and consumer advocates.

In a series of conference calls, the guideline development group defined the scope and objectives of the proposed guideline. During the 12 months devoted to guideline development ending in September 2012, 2 in-person meetings were held during which electronic decision support (BRIDGE-

Wiz) software was used to facilitate the creation of actionable recommendations and action statement profiles. Internal electronic review and feedback for each guideline draft was used to ensure accuracy of content and consistency with standardized criteria for creating clinical practice guidelines.

After completing the action statement profile, the group rated their level of confidence in the aggregate evidence underpinning the recommendation as "high," "medium," or "low" based on the quantity, consistency, precision, and generalizability of the evidence. Any differences of opinion among guideline development group members concerning any aspect of the action statement, accompanying profile, or amplifying text were also documented with a rating of "none," "minor," or "major," with an explanation of any differences that occurred.

American Academy of Otolaryngology—Head and Neck Surgery Foundation (AAO-HNSF) staff used the Guideline Implementability Appraisal and Extractor software to appraise adherence of the draft guideline to methodological standards, ensure clarity of recommendations, and predict potential obstacles to implementation. Guideline panel members received summary appraisals in September 2012 and modified an advanced draft of the guideline based on the appraisal.

Rating Scheme for the Strength of the Recommendations

Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong Recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation) and that the quality of the supporting evidence is excellent (grade A or B). [*] In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade B or C). [*] In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.	Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	An option means that either the quality of evidence that exists is suspect (grade D) [*] or that well-done studies (grade A, B, or C) [*] show little clear advantage to one approach versus another.	Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.
No Recommendation	No recommendation means there is both a lack of pertinent evidence (grade D) [*] and an unclear balance between benefits and harms.	Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

^{*}See the "Rating Scheme for the Strength of Evidence" field for definitions of evidence grades.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The final guideline draft underwent extensive external peer review. Comments were compiled and reviewed by the panel's chair; a modified version of the guideline was distributed and approved by the guideline development panel.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Recommendations contained in the guideline are based on the best available data published through September 2012. Where data were lacking, a combination of clinical experience and expert consensus was used.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate use and management of tympanostomy tubes in children
- The primary benefits of tympanostomy tube placement are reduced prevalence of middle ear effusion resulting in improved hearing, improved patient and caregiver quality of life, and possible improved language acquisition through better hearing across the speech frequencies, binaural processing, and sound localization.

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

Potential Harms Associated with Use of Tympanostomy Tubes

Anesthesia Risks

Potential benefits of tubes must be balanced against the associated risks, including general anesthesia and direct tube-related sequelae. The incidence of anesthesia-related death for children undergoing diverse surgical procedures (including tympanostomy tube insertion) ranges from 1 in 10,000 to 1 in 45,000 anesthetics delivered. In the perioperative period, children are more prone to laryngospasm and bronchospasm than adults are, which may increase the risk of anesthetic complications.

Tympanostomy Tube Sequelae

- The most common sequelae of tympanostomy tubes is otorrhea (TTO), seen in approximately 16% of children within 4 weeks of surgery and 26% of children at any time the tympanostomy tube remains in place. Most tympanostomy tubes used in the United States remain in place for 12 to 14 months, during which approximately 7% of children experience recurrent TTO.
- Other complications include blockage of the tympanostomy tube lumen in 7% of intubated ears, granulation tissue in 4%, premature extrusion of the tympanostomy tube in 4%, and tympanostomy tube displacement into the middle ear in 0.5%.

Longer-term Sequelae

- Longer-term sequelae of tympanostomy tube placement include visible changes in the appearance of the tympanic membrane.

Myringosclerosis consists of white patches in the ear drum from deposits of calcium and can be seen while the tube is in place or after extrusion. Myringosclerosis is more common in intubated ears than in controls is usually confined to the drum, and very rarely causes clinically significant hearing issues.

- Tympanic membrane atrophy, atelectasis, and retraction pockets are all more commonly observed in children with otitis media who are treated with tympanostomy tubes than in those who are not.
- These tympanic membrane changes, with the exception of tympanosclerosis, appear to resolve over time in many children and rarely require medical or surgical treatment. Persistent perforation of the tympanic membrane is seen in 1% to 6% of ears after tympanostomy tubes are placed. When perforations persist, surgical closure may be required.

Impact on Hearing

The long-term impact of tympanostomy tubes on hearing acuity has been studied. Children in a longitudinal otitis media study had their hearing measured at 6 years of age. Children who had tympanostomy tubes in the past had a 1- to 2-dB worsening in hearing thresholds compared with those who did not have tympanostomy tubes. This hearing worsening is trivial, and it should be noted that the mean hearing levels (HL) in these children with or without a history of tubes was 4.3- to 6.2-dB HL, which is well within the range of normal hearing. Another study of children aged 8 to 16 years who had participated in a randomized controlled trial of tympanostomy tubes versus medical treatment for otitis media 6 to 10 years prior found hearing thresholds 2.1 to 8.1 dB poorer in those children who had a history of tympanostomy tubes. The greatest hearing deficits were seen when testing low-frequency tones.

Potential Harms Associated with Action Statements

- Not performing tympanostomy tube insertion in children with a single episode of otitis media with effusion of less than 3 months' duration, from the date of onset (if known) or from the date of diagnosis (if onset is unknown) may result in delayed intervention in children who do not recover spontaneously and/or in children who develop recurrent episodes of middle ear effusion.
- Performing tympanostomy may result in risk of anesthesia, sequelae of the indwelling tympanostomy tubes (e.g., otorrhea, granulation tissue, obstruction), complications after tube extrusion (myringosclerosis, retraction pocket, persistent perforation), failure of or premature tympanostomy tube extrusion, tympanostomy tube medialization, procedural anxiety and discomfort.
- Not performing tympanostomy tube insertion in children with recurrent acute otitis media who do not have middle ear effusion in either ear at the time of assessment for tube candidacy may result in delay in intervention for children who eventually require tympanostomy tubes and the need for systemic antibiotics among children who continue to have episodes of recurrent acute otitis media.
- Use of topical antibiotic eardrops only, without oral antibiotics, for children with uncomplicated acute tympanostomy tube otorrhea may result in potential difficulties in drug delivery to the middle ear if presence of obstructing debris or purulence in the ear canal.
- Not encouraging routine, prophylactic water precautions (use of earplugs or headbands; avoidance of swimming or water sports) for children with tympanostomy tubes may result in a slight increase in otorrhea rates in some children.

Qualifying Statements

Qualifying Statements

- Most high-quality evidence on tympanostomy tube efficacy and adverse events comes from published studies that have been conducted using otherwise healthy children without comorbid illnesses, syndromes, or disorders. Therefore, the Guideline Development Group (GDG) has included several recommendations in the guideline related to managing children with coexisting conditions that may put them at added risk for speech, language, or developmental sequelae of otitis media. These recommendations must therefore be interpreted with the caveat that they may involve extrapolations from studies performed in otherwise healthy children.
- Guidelines are not intended to supersede professional judgment but rather may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance. Less frequent variation in practice is expected for a "strong recommendation" than might be expected with "recommendation." "Options" offer the most opportunity for practice variability. Clinicians should always act and decide in a way that they believe will best serve their patients' interests and needs, regardless of guideline recommendations. They must also operate within their scope of practice and according to their training. Guidelines represent the best judgment of a team of experienced clinicians and methodologists addressing the scientific evidence for a particular topic.
- This clinical practice guideline is provided for information and educational purposes only. It is not intended as a sole source of guidance in managing children with tympanostomy tubes or being considered for tympanostomy tubes. Rather, it is designed to assist clinicians by providing an evidence-based framework for decision-making strategies. The guideline is not intended to replace clinical judgment or establish a protocol for all individuals with this condition and may not provide the only appropriate approach to diagnosing and managing this

program of care. As medical knowledge expands and technology advances, clinical indicators and guidelines are promoted as conditional and provisional proposals of what is recommended under specific conditions but are not absolute. Guidelines are not mandates; these do not and should not purport to be a legal standard of care. The responsible physician, in light of all circumstances presented by the individual patient, must determine the appropriate treatment. Adherence to these guidelines will not ensure successful patient outcomes in every situation. The American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS), Inc. emphasizes that these clinical guidelines should not be deemed to include all proper treatment decisions or methods of care or to exclude other treatment decisions or methods of care reasonably directed to obtaining the same results.

Implementation of the Guideline

Description of Implementation Strategy

Implementation Considerations

This clinical practice guideline is published as a supplement to *Otolaryngology—Head and Neck Surgery*, to facilitate reference and distribution. A full-text version of the guideline will also be accessible, free of charge, at <http://www.entnet.org> . In addition, all American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF) guidelines are now available via the Otolaryngology—Head and Neck Surgery app for smart phones and tablets. The guideline will be presented to American Academy of Otolaryngology-Head and Neck Surgery members as a miniseminar at the AAO-HNSF Annual Meeting & OTO EXPO. Existing brochures and publication by the AAO-HNSF will be updated to reflect the guidelines recommendations.

The Guideline Development Group (GDG) agreed that the recommendations likely to generate the most discussion among clinicians are the 2 statements regarding tympanostomy tube insertion for recurrent acute otitis media (AOM). The GDG has distinguished for the first time between recurrent AOM with and without persistent middle ear effusion (MEE), with tubes indicated only when the effusion persists. This rationale is supported by existing randomized controlled trials and evidence about the natural history of recurrent AOM when effusion is absent but is not part of the management paradigm for most practicing clinicians. Education and supporting materials will be required to justify why a child with recurrent AOM but no middle ear effusion is unlikely to benefit from tympanostomy tubes, despite parental/caregiver pressure or "traditional" practice.

In the circumstance described, along with other situations in which tympanostomy tubes are not initially recommended, educational materials should be developed to help caregivers and families understand the benefits of watchful waiting instead of immediate tube insertion. This material should include the importance of follow-up visits and monitoring for signs or symptoms related to otitis media with effusion or recurrent AOM that would make the child a potential candidate for tubes and benefit from reassessment by the clinician. Information should also be provided to assist caregivers in detecting child behavior that would suggest a hearing loss is present, which might include the questions for reported hearing difficulty in Table 7 of the original guideline document.

Another implementation concern relates to using topical antibiotic eardrops for acute, uncomplicated tympanostomy tube otorrhea (TTO). The drops must reach the middle ear space to have the desired benefits, but this can occur only if the drops pass freely through the ear canal and penetrate the tympanostomy tube. An educational video, or other teaching aid, should be developed to illustrate how parents/caregivers should instill the drops (e.g., the importance of "pumping" the tragus) and how parents/caregivers or clinicians can clean otorrhea and crusts from the ear canal and adjacent skin, if necessary.

Implementation Tools

Clinical Algorithm

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Wall Poster

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Rosenfeld RM, Schwartz SR, Pynnonen MA, Tunkel DE, Hussey HM, Fichera JS, Grimes AM, Hackell JM, Harrison MF, Haskell H, Haynes DS, Kim TW, Lafreniere DC, LeBlanc K, Mackey WL, Nettekville JL, Pipan ME, Raol NP, Schellhase KG. Clinical practice guideline: tympanostomy tubes in children. *Otolaryngol Head Neck Surg*. 2013 Jul;149(1 Suppl):S1-35. [138 references] [PubMed](#)

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Committee

American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) Foundation Guideline Development Panel

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Financial Disclosures/Conflicts of Interest

Financial Disclosure and Conflicts of Interest

The cost of developing this guideline, including travel expenses of all panel members, was covered in full by the Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF). Potential conflicts of interest for all panel members in the past 2 years were compiled and distributed before the first conference call. After review and discussion of these disclosures, the panel concluded that individuals with potential conflicts could remain on the panel if they (1) reminded the panel of potential conflicts before any related discussion, (2) recused themselves from a related discussion if asked by the panel, and (3) agreed not to discuss any aspect of the guideline with industry before publication. Lastly, panelists were reminded that conflicts of interest extend beyond financial relationships and may include personal experiences, how a participant earns a living, and the participant's previously established "stake" in an issue.

Disclosures

Competing Interests: Seth R. Schwartz, research funding from Cochlear Corporation and instructor for temporal bone course with Medtronic. Melissa A. Pynnonen, consultant for K. Storz. David E. Tunkel, consultant for Medtronic ENT. Alison M. Grimes, husband is an employee at Starkey Labs. Jesse M. Hackell, advisory panel member for Sonovion Inc; speakers bureau at Glaxo Smith Kline, Inc.; expert witness in medical malpractice cases. David S. Haynes, advisory board member for Cochlear Corporation, Anspach Company, Advanced Bionics, Grace Medical. James L. Nettekville, consultant for Medtronic.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the [American Academy of Otolaryngology – Head and Neck Surgery Web site](#) .

Availability of Companion Documents

The following are available:

- Rosenfeld RM, Schwartz SR, Pynnonen MA, Tunkel DE, Hussey HM, Fichera JS, Grimes AM, Hackell JM, Harrison MF, Haskell H, Haynes DS, Kim TW, Lafreniere DC, LeBlanc K, Mackey WL, Nettekville JL, Pipan ME, Raol NP, Schellhase KG. Clinical practice guideline: tympanostomy tubes in children – executive summary. *Otolaryngol Head Neck Surg*. 2013 Jul;149(1):8-16. Electronic copies:

Available from the [SAGE Journal Online Web site](#) .

- Clinical practice guideline tympanostomy tubes in children. Podcast Part 1 and 2. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS). 2013 Jul. Available from the [SAGE Journal Online Web site](#) .
- Research gaps - tympanostomy tubes in children. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS). 2013 Jul. Electronic copies: Available from the [AAO-HNS Web site](#) .
- AAO-HNSF clinical practice guideline: tympanostomy tubes in children. Fact sheet. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS). 2013 Jul. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the [AAO-HNS Web site](#) .
- Jump in. It's safe to swim. Tympanostomy tubes guideline poster. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS). 2013 Jul. copies: Available in Portable Document Format (PDF) from the [AAO-HNS Web site](#) .
- Rosenfeld RM, Shiffman RN, Robertson P. Clinical practice guideline development manual, third edition: a quality-driven approach for translating evidence into action. Otolaryngol Head Neck Surg. 2013;148(Suppl 1):S1-55. Electronic copies: Available from the [SAGE Journal Online Web site](#) .

Patient Resources

The following is available:

- Clinical practice guideline: tympanostomy tubes in children. Patient leaflet. Alexandria (VA): American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNS). 2013 Jul. Electronic copies: Available from the [American Academy of Otolaryngology - Head and Neck Surgery Web site](#) .

In addition, a sample education sheet for tympanostomy tube care, which may be modified to suit individual needs, is included in the [original guideline document](#) .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on September 10, 2013. The information was verified by the guideline developer on October 9, 2013.

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